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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,786	04/04/2001	Gerald W. Mills	723.035US1	1321

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EXAMINER	
JUNG, WILLIAM C	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SD

Office Action Summary	Application No.	Applicant(s)	
	09/825,786	MILLS ET AL.	
	Examiner	Art Unit	
	William Jung	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-26 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-26 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 10-26 and 29-32 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 10-26 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by ***Franck et al*** (US 6,529,765 B1).

Franck et al anticipate all claimed features in claims 10-26 and 29-32.

Claims 10, 20, and 22: Franck et al disclose a method and apparatus where an alignment system as shown in figures 3, 5, 7, 9, and 10 where the system comprises a base 330affixed to a patient's surface, a insertion guide 710 (in figure 9) having an opening and insertion axis through

the opening, an adjustable joint attached to a distal end of the insertion guide, and coupled to the base plate 724, a local adjustment device attached to the adjustable joint 840, an actuator coupled to the local adjustment device, and a control module 580 in remote communication with the actuator and in communication with the imaging device 560 to alignment the insertion axis with the target location (col. 3, line 65 – col. 4, line 65; col. 7, line 57 – col. 8, line 47; col. 8, line 50 – col. 9, line 6; col.11, line 40 – col. 12, line 41).

Claim 11: Franck et al disclose the control module as described above is a workstation. However, the miniaturization of computer (microcomputer) is purely a design choice since the control function of the control module does not change with the size of the control module.

Claim 12: Franck et al disclose that the image-guided procedure such as one described above can be used with variety of medical imaging system including MRI device (col. 1, lines 43-50).

Claims 13-15: Franck et al disclose fiducial markers 340 where the markers provide first reference coupled to the insertion guide to locate the insertion axis in 3D space relative to the patient (col. 8, lines 3-31).

Claims 16 and 17: Franck et al disclose a reference device 730 in which it provides LED to locate the insertion axis in 3D space relative to the patient (col. 12, lines 1-13).

Claim 21: Franck et al as shown in figures 3, 5, 7, and 9 where the coupling at he base includes attached the base directly to the skull of the patient (col. 8, lines 5-11).

Claims 30 and 31: Franck et al further disclose the local adjustment described above where it includes slide coupled to the insertion guide 850 as shown in figure 10.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Franck et al*** as applied to claims 10, 30, and 31 above, and further in view of ***Truwit*** (6,206,890 B1).

Franck et al substantially disclose all claimed features in claims 29 and 32. However, Franck et al do not explicitly disclose in writing the structure of the actuator being a ball and socket joint. In figures 11, 17c, and 19, Franck et al illustrates socket join with round structure 914 in round shape. Although, Frank et al's disclosure is silent in ball and socket joint, it would be obvious to view figure 11 as ball and socket without complete drawing of 914 where ball and socket joint is used in the art as evident by Truwit's (6,206,890 B1) use of the same structure for the insertion guide (see figure 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Franck et al with the ball and socket joint actuator as disclosed by Truwit to provide accurate actuation of the insertion guide as disclosed by Franck et al.

6. Claims 18, 19, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Franck et al*** as applied to claims 10 and 20 above, and further in view of ***Lee et al*** (US 3,893,449).

Franck et al substantially disclose of all claimed invention in claims 18, 19, and 23-26. However, Franck et al do not disclose rotary motor coupled to the local adjustment device and

the control of the device via potentiometer. Lee et al discloses of an imaging device placed on a patient with remote control of the device to align the imaging device to an appropriate location. Lee et al also teaches that the location of the medical device such as ultrasound is referenced to identify the position using potentiometer (col. 1, line 59 – col. 2, line 11). Lee et al also disclose in figures 2 and 11 where the control mechanism includes pin joint actuator with rotary motor with rotating cable drive (col. 5, lines 36-64). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Franck et al's aligning imaging device to teachings of Lee et al's position referencing system to achieve the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WC
May 13, 2005

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